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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/044,405

01/11/2002

Paul H. Stypulkowski

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07/02/2004

MEDTRONIC, INC.

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MINNEAPOLIS, MN 55432-5604

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 07/02/2004 *6*

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,405

Applicant(s)

STYPULKOWSKI, PAUL H.

Examiner

George R Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-23 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4, 5.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 12/30/03 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein regarding the FR 2500309 document has not been considered.

Claim Objections

Claims 1-17 and 21-23 are objected to because of the following informalities listed below. Appropriate correction is required.

In claim 1, line 6, "of a second stimulation parameter" should be "of a second of said stimulation parameters" since the stimulation parameters have been recited in line 2.

In claim 7, "wherein varying the first stimulation parameter to produce a neuron-firing pattern" should first set forth in claim 6 that the firing pattern is produced by varying the first stimulation parameter.

In claims 10 and 13, the means for varying or step of varying at least a first stimulation parameter should be "means for pseudo-randomly varying" or "pseudo-randomly varying" since the claims have a further step/element "based upon having pseudo-randomly varied".

Claim 14 should be canceled since it contains the same elements as in claim 13.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5-15, and 17-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gliner (US 2002/0055762). Gliner shows in figures 6 and 8-10 the random variation of the frequency and changing of the amplitude based on the frequency within predetermined limits (pseudo-randomly varying) and strength-duration curves for the varying stimulation parameters to follow. For claims 6 and 7, since Gliner randomly changes the frequency and amplitude and does it over a wide range (as seen in figures 8 and 9), he inherently will produce a neuron-firing pattern having a plurality of different interspike intervals and selected from the group of normal,

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skew-right, skew-left, or bimodal. In addition, a varying of electrode polarity firing conditions would inherently change a spatial pattern of neurons affected since the electrodes are positioned in different locations. Also, the varying inherently avoids development of physiological tolerance due to the changing stimulation parameters over the large predetermined range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gliner.

Gliner discloses the claimed invention except for measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neural stimulation system/method as taught by Gliner, with a measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved since it was known in the art that neural stimulation systems/methods have steps for measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved in order to maintain the stimulation capability of the electrical stimulation pulses substantially constant to provide a desired outcome.

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Claims 1 and 8-23 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mouine et al (2004/102820). Mouine states in paragraph 49 that the amplitude, frequency, and pulse duration are randomly varied to maintain a predetermined average and that these parameters define the amount of charge delivered to the nerve and therefore will inherently change a second stimulation parameter when the first stimulation parameter is changed in order to maintain the predetermined average. In addition, Mouine uses a disconnect module to attach the electrodes and to leave the electrodes in the body and therefore must inherently have some sort of lead to attach to the module.

In the alternative, Mouine discloses the claimed invention except for the changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neurostimulation system/method as taught by Mouine, with a changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter since it was known in the art that neurostimulation systems use a changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter to maintain the stimulation capability of the stimulation pulses substantially constant to provide therapy to the patient.

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Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Archer is another example of an implantable device that randomly varies stimulation parameters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE
June 27, 2004


GEORGE R. EVANISKO
PRIMARY EXAMINER
6/27/4